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Does the treatment of anxiety in children with ADHD improve outcomes?

Submission date
10/09/2015

Recruitment status
No longer recruiting

Registration date
29/09/2015

Overall study status
Completed

Last Edited
10/06/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Attention deficit hyperactivity disorder (ADHD) is a common disorder that affects behaviour. ADHD can present in a number of ways, but common symptoms include a short attention span, restlessness, hyperactivity and impulsiveness. It has been found that up to half of children with a diagnosis of ADHD also have problems with anxiety. The exact reason for this is unknown, but it may be because the symptoms of ADHD are very disruptive to daily life and can make life a lot more stressful. As well as affecting the children's quality of life, it has been found that their parents are more likely to suffer from mental health difficulties, such as anxiety and depression. There is a lot of evidence to suggest that anxiety problems in children with ADHD may be underreported, as the symptoms of anxiety can be very similar to the ADHD symptoms. This can mean that many children are not treated, and their anxiety problems can get even worse. There are many ways to treat anxiety; however behavioural treatments such as cognitive behavioural therapy (CBT) may be preferable to medication for the children's parents. The aim of this study is to find out how effective a CBT programme, designed to help children to cope better with their anxiety, is for children suffering from ADHD.

Who can participate?
Children aged 8 to 12 years with a diagnosis of ADHD, who show signs of anxiety.

What does the study involve?
Participants are randomly allocated into the treatment group, or the usual care group. Those in the treatment group attend 10 sessions with a clinician to learn strategies to help them to manage their feelings of anxiety. Those in the usual care group receive access to usual care for their ADHD, but no extra help with their feelings of anxiety. After five months, the parents and teachers complete questionnaires about the children's feelings of anxiety and behaviour. The wellbeing and behaviour of the parents are also assessed using questionnaires at this timepoint.

What are the possible benefits and risks of participating?
Benefits of participating may include an improvement in anxiety, which could lead to improvements in the child's behaviour and wellbeing. There are no risks of participating in the study.

Where is the study run from?
Murdoch Childrens Research Institute (Australia)

When is the study starting and how long is it expected to run for?
September 2015 to December 2019

Who is funding the study?
1. Murdoch Childrens Research Institute (Australia)
2. Sidney Myer Fund and Myer Foundation (Australia)
3. The National Health and Medical Research Council (Australia)

Who is the main contact?
Dr Emma Sciberras
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Does the treatment of anxiety in children with ADHD improve outcomes? A large-scale randomised controlled trial

Study objectives
Cognitive behavioural therapy is superior to standard care for the treatment of anxiety in children with ADHD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Royal Children's Hospital Human Research Ethics Committee, 09/09/2015, ref: 35164

Study design
Single-centre randomised controlled trial of a cognitive behavioural treatment versus usual care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
1. Attention deficit hyperactivity disorder (ADHD)
2. Anxiety

Interventions
Children in the intervention arm will receive 10 sessions of cognitive behavioural therapy delivered by study trained psychologists, while the control group will continue to access usual care for management of their ADHD.

Intervention Type
Behavioural

Primary outcome measure
Parent report of whether the child meets criteria for an anxiety disorder (separation anxiety disorder, social phobia, or generalised anxiety disorder) 5 months post-randomisation measured by the Anxiety Disorders Interview Schedule for Children 5.

Secondary outcome measures
Secondary outcome measures as of 05/10/2016:
1. Anxiety: Parent and child report of child anxiety symptoms as measured by the Spence Child Anxiety Scale and the Child Anxiety Life Interference Scale; teacher report of anxiety symptoms

as measured by the School Anxiety Scale (all measured at baseline, 5 and 12 months post randomisation). Parent report of whether the child meets criteria for an anxiety disorder (separation anxiety disorder, social phobia, or generalised anxiety disorder) 12 months post-randomisation measured by the Anxiety Disorders Interview Schedule for Children 5
2. ADHD symptoms as measured by the ADHD Rating Scale IV (parent and teacher report measured at baseline, 5 and 12 months post randomisation)
2. Psychosocial quality of life as measured by the CHU-9D (parent and child report measured at baseline, 5 and 12 months post randomisation)
3. Behaviour as measured by the Strengths and Difficulties Questionnaire (parent and teacher report measured at baseline, 5 and 12 months post randomisation)
4. Executive functioning as measured by the NIH cognitive toolbox (blinded, direct assessment at baseline, 5 and 12 months post randomisation)
5. Parent mental health as measured by the K6 (measured at baseline, 5 and 12 months post randomisation)
6. Parenting behaviours as measured by a series a questions from the Longitudinal Study of Australian Children (measured at baseline, 5 and 12 months post randomisation)

Original secondary outcome measures:
1. Anxiety: Parent and child report of child anxiety symptoms as measured by the Spence Child Anxiety Scale and the Child Anxiety Life Interference Scale; teacher report of anxiety symptoms as measured by the School Anxiety Scale (all measured at baseline and 5 months post randomisation).
2. ADHD symptoms as measured by the ADHD Rating Scale IV (parent and teacher report measured at baseline and 5 months post randomisation)
2. Psychosocial quality of life as measured by the PedsQL 4.0 (parent and child report measured at baseline and 5 months post randomisation)
3. Behaviour as measured by the Strengths and Difficulties Questionnaire (parent and teacher report measured at baseline and 5 months post randomisation)
4. Executive functioning as measured by the NIH cognitive toolbox(blinded, direct assessment at 5 months post randomisation)
5. Parent mental health as measured by the K6 (measured at baseline and 5 months post randomisation)
6. Parenting behaviours as measured by a series a questions from the Longitudinal Study of Australian Children (measured at baseline and 5 months post randomisation)

Overall study start date
29/09/2015

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Children aged 8 - 12 years
2. Caregiver report of ADHD symptoms meeting Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria for ADHD (child also needs to have been previously diagnosed with ADHD by a paediatrician)
3. Caregiver report of anxiety symptoms meeting Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria for Separation Anxiety Disorder, Generalised Anxiety Disorder, or Social Phobia

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
228

Key exclusion criteria
1. Receiving specialised treatment for anxiety from a psychologist or psychiatrist. Participants who are taking medication for anxiety can participate provided they are still experiencing significant anxiety symptoms and have been on stable medication for a minimum of six weeks.
2. Major illness or disability.
3. Non-English speaking

Added 05/10/2016:
4. A score of 15 or greater on the Social Communication Questionnaire, a measure of autism symptoms

Date of first enrolment
06/10/2015

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Australia

Study participating centre
Murdoch Childrens Research Institute (MCRI)
The Royal Children's Hospital
Flemington Rd
Parkville
Australia
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Sponsor information

Organisation
Murdoch Childrens Research Institute (MCRI)

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Sponsor type
Research organisation

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ROR
https://ror.org/048fyec77

Funder(s)

Funder type
Research organisation

Funder Name
Murdoch Childrens Research Institute

Funder Name
Sidney Myer Fund and Myer Foundation

Alternative Name(s)
Sidney Myer Fund & The Myer Foundation, Sidney Myer Fund and the Myer Foundation, Myer Foundation and Sidney Myer Fund, Myer Foundation & Sidney Myer Fund's

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
Australia

Funder Name
The National Health and Medical Research Council

Results and Publications

Publication and dissemination plan
The results will be published in a peer reviewed journal and also presented at international conferences.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from emma.sciberras@deakin.edu.au

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/11/2019	10/06/2020	Yes	No